REMARKS

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

Claims 1, 7, 14, and 18 have been amended. Claims 11-13, 19-20, and 24-30 have been canceled without prejudice, and claims 31-47 have been added. It is believed that new claims 31-47 are supported by the originally filed application. For example, support for claims 31-47 can be found in FIGS. 1, 9, 11, 13 and 15 of the drawings and pages 8-15 of the specification as well as elsewhere throughout the application. Consequently, claims 1-10, 14-18, 21-23, and 31-47 are currently pending and under consideration.

Independent Claim 1

To conserve claim fees as well as provide further protection, independent claim 1 has been amended to cover the features previously recited in claims 1 and 7. Claim 7 has been amended so as to now depend upon claim 1, and dependent claim 31 has been added to recite the aperture previously recited in claim 1. Duplicate dependent claims have been canceled. Independent claim 1 was previously "rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott Laboratories (WO 98/24366) in view of Terumo (WO 00/40150)." It is believed that independent claim 1 as currently amended is allowable over the references of record. For example, together Abbott Laboratories and Terumo fail to disclose or suggest a test strip that includes "a sealing member on the bottom surface and positioned to contact and seal with the skin when said body is pressed against the skin" as is recited in claim 1. As should be appreciated from reviewing the present application, the sealing member helps to prevent fluid leakage underneath the test strip, but by sealing against the skin, the sealing member becomes contaminated with body fluid, such as blood. However, since the sealing member is part of the test strip, it is disposed of with the rest of the test strip so as to minimize any hygienic problems.

On page 2 of the Office Action, it was purported that the nosepiece 3000 in FIG. 32 of Abbott Laboratories corresponded to the recited sealing member. However, it should be recognized that the nosepiece assembly 3000 in Abbott Laboratories does not correspond because it is not part of a test strip. Rather, the nosepiece 3000 is incorporated into a lancing device, such as illustrated in FIG. 2 (nosepiece 30). "Although the PTO must give claims their broadest reasonable interpretation, this interpretation must be consistent with the one that those

skilled in the art would reach." In re Cortright, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999); see, Manual of Patent Examining Procedure (MPEP) §2111. The preamble of claim 1 clearly identifies that the recited feature concerns a "test strip", and the body of claim 1 further requires that the sealing member is on the bottom of the test strip. One of ordinary skill in the art would not have reasonably concluded that the nosepiece 3000 (or any component thereof) was part of the test strip or glucose detector (40 in FIG. 4 or 1100 in FIG. 21A). Instead, one of ordinary skill in the art would have found that the nosepiece 3000 and glucose detector 40 are in fact separate and distinct components and that the glucose detector 40 lacks the sealing member recited on claim 1. Teurmo likewise fails to remedy this missing feature. Moreover, there would have been no motivation at the time of the invention for one of ordinary skill in the art to arrive at the above-mentioned missing feature, except through impermissible hindsight. For these and other reasons, claim 1 and its dependent claims are allowable over the references of record.

Independent Claim 14

To conserve claim fees as well as provide further protection, independent claim 14 has been amended to cover the features previously recited in claims 14 and 18. Claim 18 has been amended so as to now depend upon claim 14, and dependent claim 32 has been added to recite the aperture previously recited in claim 14. Duplicate dependent claims have been canceled. Independent claim 14 was previously "rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott Laboratories (WO 98/24366) in view of Terumo (WO 00/40150)." However, both of these references even when combined together fail to disclose all of the features recited in claim 14, such as "said body further including a recessed surface extending between the inlet opening and the bottom surface." In the Office Action, cavity 3010 of the nosepiece 3000 in FIG. 32 of Abbott Laboratories was alleged as corresponding to the recited recessed surface. Again, it is submitted that one of ordinary skill in the art would have reasonably found the nosepiece 3000 as well as its cavity 3010 to not be incorporated into a test strip, but rather, one of ordinary skill in the art would have found the cavity 3010 to be incorporated in the lancing device. In other words, even giving claim 14 its broadest interpretation, one of ordinary skill in the art would have found it unreasonable to conclude that the cavity 3010 of the nosepiece 3000 was somehow part of a test strip. Likewise, the test strip 32 in Terumo lacks such a recess.

Except through impermissible hindsight, there would have been no motivation to place such a recessed surface on a test strip. For these and other reasons, claim 1 and its dependent claims are allowable over the references of record.

Independent Claim 33

New independent claim 33 has been added to provide further protection as well as highlight some unique features. It is believed that claim 33 is allowable over the references of record. For example, both Abbott Laboratories and Terumo fail to disclose or even suggest the recited combination of the lancing device and test strip as recited in claim 33 and in particular "a sealing member projecting outwardly from the bottom surface of the test strip proximal the inlet opening and positioned to seal with the skin when the test strip is pressed against the skin to retain the body fluid at the inlet opening; and wherein the test strip with the sealing member is configured to be unloaded from the lancing device as a single disposable unit." As mentioned before, neither Abbott Laboratories nor Terumo disclose a test strip with a sealing member. Again, one skilled in the art would have found it unreasonable to consider the nosepiece 3000 in Abbott Laboratories as being part of a test strip. As noted before, having the sealing member on the test strip helps to reduce the risk of contamination because the test strip is disposed of after each use. In contrast, the nosepiece 3000 in Abbott Laboratories is part of a lancing device, and thus, the nosepiece 3000 needs to be thoroughly cleaned and sterilized after each test to avoid any contamination and/or hygienic problems. Moreover, one ordinarily skilled in the art at the time of the invention would have lacked any motivation to place a sealing member on a test strip. For these and other reasons, claim 33 and its dependent claims are allowable over the references of record.

Independent Claim 40

New independent claim 40 has also added to provide further protection as well as highlight some unique features. It is believed that claim 40 is allowable over the references of record. For example, both Abbott Laboratories and Terumo fail to disclose or even suggest the recited combination of the lancing device and test strip as recited in claim 40, in particular "the test strip having a recessed surface extending between the inlet opening and the bottom surface to inhibit contact of the body fluid on the skin with the bottom surface of the test strip; and

wherein the test strip with the recessed surface is configured to be unloaded from the lancing device as a single disposable unit." Abbott Laboratories and Terumo both fail to disclose a test strip with a recessed surface. For example, the cavity 3010 of the nosepiece 3000 in Abbott Laboratories is located on the lancing device and not on a test strip. As alluded to before, having fluid directing features like the recited recessed surface on the test strip helps to reduce the risk of contamination because the test strip is disposed of after each use. Terumo likewise fails to disclose such a feature. For these and other reasons, independent claim 40 and its dependent claims are allowable over the references of record.

Independent Claim 43

It also should be recognized that new independent method claim 43 is allowable over the references of record. For instance, Abbott Laboratories and Terumo fail to disclose or suggest "forming a fluid tight seal between the sealing member and the skin by pressing the sealing member of the test strip against the skin" and "disposing the sealing member of the test strip by unloading the test strip from the lancing device" as recited in claim 43. As noted before, neither reference describes utilizing a sealing member on a test strip and then disposing of the sealing member after the test strip has been used. For these and other reasons, independent claim 43 and its dependent claims are allowable over the references of record.

Independent Claim 46

It also should be recognized that new independent method claim 46 is allowable over the references of record. For instance, Abbott Laboratories and Terumo together fail to disclose or suggest "directing body fluid from the incision to the inlet opening by inhibiting contact of the body fluid to the test strip with the recessed surface" and "disposing of the test strip with the recessed surface by unloading the test strip from the lancing device" as recited in claim 46. As noted before, the test strips described in both of the references do not have such recesses and thus are incapable of directing fluid in the manner as recited. For these and other reasons, independent claim 46 and its dependent claims are allowable over the references of record.

Power of Attorney

As a housekeeping matter, it should be noted that a Power of Attorney to Prosecute Applications Before the USPTO for Roche Diagnostics Operations, Inc., and a Statement Under 37 CFR 3.73(b) for this application have been enclosed with this response in order to update the Power of Attorney to the current customer number (41577). It is believed that the requirements to update the Power of Attorney for this application have been satisfied, but if additional documentation is required, the Examiner is invited to contact the undersigned by telephone to quickly resolve the issue.

Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly solicited. If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the undersigned representative by telephone to resolve such issues.

Respectfully submitted,

By /Charles P. Schmal #45,082/

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